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EXAMINER	
RAMDHANIE, BOBBY	
ART UNIT	PAPER NUMBER
1797	
MAIL DATE	DELIVERY MODE
12/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,563	PETRICH ET AL.	
	Examiner	Art Unit	
	BOBBY RAMDHANIE	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 July 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 09/17/2008 have been fully considered but they are not persuasive. The following are reasons why:

2. First, Applicant argues that the Beer-Lambert Law is valid from 0-positive infinity. The Examiner respectfully disagrees. Applicant has not disclosed any extinction coefficients for any of the peaks in the Drawings which would support values above 1.0 absorbance units. Further, it is well known in the art that values above 1.0 are “suspect” (open to enablement issues) since this may be an artifact of the background which is shown in the Drawings and it is known that signals above an absorbance unit of 1.0 are non-linear (See Attachment Chem434/UV/Vis). Further, Applicants have used the Drawings to demonstrate metabolic syndrome using a "dotted line." This is not clearly shown in the Drawings of Figure 3.

3. Second, Applicant's argue in their remarks that “hypertension” and “being overweight” can not be measured by clinical analysis of blood. The very next paragraph applicants state that their method and system **ARE CAPABLE** of measuring “hypertension” and “being overweight” in **blood**. These two statements contradict each other. The Examiner believes that in any given blood sample that these components which contribute to hypertension or someone being overweight inherently exist. The method and system as claimed, are not distinguishable from the prior art cited. Examiner believes applicants are claiming a genus method when the species of the method is already known in the prior art of record.

4. According to the American Heart Association, metabolic syndrome comprises a number of omitted factors from which the applicants claim make up “metabolic syndrome. (See Attachment and in particularly, “What is metabolic syndrome and How is metabolic Syndrome diagnosed?).” None of these other factors are shown in the Drawings.

5. Further to add to confusion, Applicants have submitted drawings to support their claims and remarks that states their method and system are capable of observing “metabolic syndrome” and in particular, “high blood pressure" and "being overweight." Neither of the two latter items are disclosed in the Drawings. The Specification does not enable one of ordinary skill to be able to point to a specific peak in the chromatograms of Figure 3 and definitively say that this peak represents the contributing factor of blood pressure (hypo/hypertension, such as a high or low blood pressures of 120/80 or 170/100), triglycerides, cholesterol, or the being overweight components of metabolic syndrome, etc. Applicants have also not disclosed any of the factors they allegedly claim make up metabolic syndrome in the Figure 3.

6. Although the reference is silent about metabolic syndrome, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben Venue Laboratories,* 58 USPQ2d 1508 (CAFC 2001). “It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable.” *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Granting a patent on the discovery of an unknown but inherent function would remove

from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

7. On this record, it is reasonable to conclude that the same method and system disclosed in the claims for the genus method of determining metabolic syndrome from a blood sample would read upon the species method for determinations of blood substrate concentrations of Janatsch and/or the combination of Janatsch and Mueller-Dethlefs). The claims of the instant application are anticipated and/or rendered obvious over the cited prior art. The fact that Applicant may have discovered yet another beneficial effect from the species method and system set forth in the prior art does not mean that they are entitled to receive a patent on the genus method.

8. Applicants argue that there is nothing in Janatsch that discloses metabolic syndrome, yet applicants *implicitly admit* on the record (see Remarks, under Anticipation by Janatsch NPL, second paragraph) that the method *is the same* as the applicant's instant method and system. Applicants then attempt to disclose unexpected results from the same method in order to distinguish the instant claims from the prior art cited, which again applicants have merely discovered and are claiming a new benefit of an old process – of which cannot render the process again patentable.

9. Applicants further argue about the sufficiency of diagnosis of the genus method (method of screening for metabolic syndrome), yet no where in the claim language is the word, "diagnosis" for anything. This argument is moot because applicants are not claiming to a method of diagnosis.

10. Lastly, applicants claim that the classification unit for classifying the sample according to metabolic syndrome is not the same as the one in Janatsch and/or Mueller-Dethlefs. Applicants have defined their classification unit as a microprocessor unit according to a multi-component analysis taking into account information from a plurality of wavelengths or wavelength regions. The Examiner respectfully disagrees. The unit of Janatsch is capable of performing this very function.

Response to Amendment

Drawings

11. The drawings are objected to because Figure 3 shows an absorbance spectra with absorbance units greater than 1. Any values above an absorbance unit of 1 is considered to be invalid based on the Beer-Lambert Law. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If

the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 28, 29, 31-37, and 41-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Janatsch et al (Anal. Chem. 1989). Regarding Claim 28, Janatsch teaches a method for screening biological sample for the presence of the metabolic syndrome in the sample donors, the method comprising: A) irradiating the biological sample by radiation (Page 2016, Right Column); B). Capturing the radiation which has interacted with the biological sample (Page 2016, Right Column); C). Evaluating the captured radiation for spectral characteristics (Page 2016 Right Column); and D). Classifying the biological sample according to the presence of the metabolic syndrome based on the biological sample's spectral characteristics (Page 2016, Right Column).

14. For Claim 29, Janatsch et al teaches a method according to claim 28, wherein the radiation is infrared radiation in the wavelength range of 2.5 to 25 micrometer (Figures 1 & 2). Examiner takes the position that the range of 2.5-25 μm defines the range of 4000-400 cm^{-1}.

15. For Claim 31, Janatsch et al teaches the method according to claim 28, wherein the biological sample is blood or a blood derivative as plasma or serum (Abstract).

16. For Claim 32, Janatsch teaches the method according to claim 28, wherein the biological sample is applied to a sample carrier prior to step of irradiation (Page 2018, Right Column 1st and 2nd Paragraphs).

17. For Claim 33, Janatsch et al teaches the method according to claim 28, wherein the biological sample is dried prior to step A). (Page 2018; Right Column 1st and 2nd Paragraphs). Examiner takes the position that the drying of the sample is essential for the KBR Pellet method.

18. For Claim 34, Janatsch et al teaches the method according to claim 28, wherein the biological sample is applied to a flow cell prior to irradiation with a small thickness preferable in a range of 6 to 30 μm (Page 2017, Bottom Left Column).

19. For Claim 35, Janatsch et al teaches the method according to claim 28, wherein the captured radiation is reflected or transmitted infrared radiation or Raman scattered radiation (Title and Abstract).

20. For Claim 36, Janatsch et al teaches the method according to claim 32, wherein the carrier has a reflective surface (Page 2016, Right Column 2nd Paragraph).

21. For Claim 37, Janatsch et al teaches the method according to claim 32, wherein the carrier has an infrared-transmissive plastic foil (Page 2017; Right Column 2nd Paragraph). Examiner takes the position a Circle cell meets the structural limitations of the carrier having an infrared-transmissive foil.

22. For Claim 41, Janatsch et al teaches the method according to claim 28, wherein the classification involves the application of an evaluation function with predetermined parameters to the spectral characteristics of the biological sample of unknown classification (Page 2017; Left Column 2nd Paragraph & Right Column 3rd Paragraph).Examiner takes the position that the multivariate calibration and comparison of the property correlation data implies this instant claim.

23. For Claim 42, Janatsch et al teaches the method according to claim 28, wherein the classification comprises a multivariate evaluation (Page 2017; Left Column 2nd Paragraph).

24. For Claim 43, Janatsch et al teaches the method according to claim 28, wherein the evaluation uses spectral information from molecular vibration frequencies of the sample corresponding to a region of 1500 to 1800 wavenumbers (region II) (Figures 1 & 2).

25. For Claim 44, Janatsch et al teaches the method according to claim 28, wherein said evaluation uses spectral information from molecular vibration frequencies of the sample corresponding to a region of 2300 to 3200 wavenumbers (region II) (Figures 1 & 2).

26. For Claim 45, Janatsch et al teaches the method according to claim 28, wherein said evaluation uses spectral information from molecular vibration frequencies of the sample corresponding to a region of 1000 to 1300 wavenumbers (region I) (Figures 1 & 2).

27. For Claim 46, Janatsch et al teaches the method according to the claim 28, wherein the evaluation uses spectral information from molecular vibration frequencies of the following combinations: A). Vibration in region 1500 to 1800 wavenumbers and 2300 to 3200 wavenumbers; B). Vibration in region 1000 to 1300 wavenumbers and 2300 to 3200 wavenumbers; C.) Vibration in region 1000 to 1300 wavenumbers and 1500 to 1800 wavenumbers; D.) Vibration in region 1000 to 1300 wavenumbers, 1500 to 1800 wavenumbers and 2300 to 3200 wavenumbers (Figures 1 & 2).

28. For Claim 47, Janatsch et al teaches a system for screening biological samples for the presence of the metabolic syndrome in sample donors, comprising: A). A radiation source for irradiating the sample (Page 2016; Right Column 1st Paragraph); B). A detector for capturing radiation which has interacted with the sample (Page 2016; Right Column 1st Paragraph); C). An evaluation unit for evaluating the captured radiation for spectral characteristics (Page 2017; Right Column 2nd Paragraph); D) A classification unit for classifying the sample according to the presence of the metabolic syndrome based on the spectral characteristics (Page 2017; Right Column 2nd Paragraph).

29. For Claim 48, Janatsch et al teaches the system according to claim 47, further comprising a sample carrier onto which sample is applied prior to irradiation (Page 2017; Right Column 2nd Paragraph).

30. For Claim 49, Janatsch et al teaches the system according to claim 48, wherein the carrier has a diffusely reflective surface (Page 2016; Right Column 2nd Paragraph). Examiner takes the position that the cell has a diffusely reflective surface.

31. For Claim 50, Janatsch et al teaches the system according to Claim 47, comprising a flow cell into which a sample is applied prior to radiation (Page 2017; Right Column 2nd Paragraph). Examiner takes the position that Janatsch et al teaches the structural limitations of the system.

32. For Claim 51, Janatsch et al teaches the system according to claim ,47, wherein the radiation source and the detector are arranged to perform infrared absorption measurement or Raman scattering measurement (Page 2017; Experimental Section).

33. For Claim 52, Janatsch et al teaches the system according to claim 47, wherein the classification unit comprises a microprocessor and a program unit being programmed to perform the classification (Page 2017, Right Column 2nd Paragraph). Examiner takes the position that a Commodore PC-20 contains a processor and a program unit.

34. For Claim 53, Janatsch et al teaches the system according to claim 52, wherein the program unit being programmed with a multivariate evaluation based on parameters determined on samples of known classification (Page 2017; Left Column 2nd Paragraph).

Claim Rejections - 35 USC § 103

35. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

36. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

37. Claims 30 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janatsch et al in view of Mueller-Dethlefs (DE10027100; An English translation of this document may be found in US6868285. Rejections will be referenced to the English translation). Regarding Claim 30, Janatsch et al teaches the method according to claim 28, except wherein the radiation is visible or near infrared radiation in the wavelength range of 0.6 to 1.5 micrometer and the type of interaction is Raman scattering. Meuller-Dethlefs teaches this feature (Column 6 lines 29-31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Janatsch et al with Mueller-Dethlefs because according to Mueller-Dethlefs this would allow for continuous instead of a merely discreet monitoring of the values of the blood analysis (Column 6 lines 43-46).

38. For Claim 38, Janatsch et al teaches the method according to claim 28, comprising the following training steps for said classification: performing steps a) and b) with samples of known classification (Page 2017; 3rd Paragraph). Janatsch et al does not teach training an evaluation program so that it assigns the samples to the known classifications. It would have been obvious to one of ordinary skill in the art at the time

the invention was made to modify Janatsch et al for training an evaluation program so that it assigns the samples to the known classifications because this would only require a computer program that would run on the Commodore PC-20 system.

39. For Claim 39, Janatsch et al teaches the method according to claim 38, wherein a reference database is generated from the biological samples of known classification (Page 2017; 3rd Paragraph).

40. For Claim 40, Janatsch et al teaches the method according to claim 38, except wherein parameters of an evaluation function are set during the training. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Janatsch et al to add the parameters of an evaluation function that are set during the training because this would be used to determine peaks for the specific metabolic syndrome factor.

Telephonic Inquiries

41. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

42. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

43. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BOBBY RAMDHANIE whose telephone number is (571)270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

44. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

45. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. R./
Examiner, Art Unit 1797

/Walter D. Griffin/
Supervisory Patent Examiner, Art Unit 1797